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EXAMINER

PROUTY, REBECCA E

ART UNIT

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NOTIFICATION DATE

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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTOCommunications@hoffmanwarnick.com

In view alterations of the claims present in the after final amendment of 2/25/08 which applicants did not indicate were present and the examiner was unaware of when they were entered, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below.

The copy of the claims contained in the Appendix to the appeal brief filed 9/29/08 is correct. However, it is noted that the current claim set which was entered after-final included an alteration of claim 1 (i.e., the deletion of "a

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quantity of xylose as a" from line 5 following PHA) which the examiner was unaware of when the after-final response was entered as applicants amendment indicated this claim as being previously presented, included no marked up portions indicating an amendment and applicants remarks did not indicate that claim 1 had been altered. The examiner would not have entered the after-final amendment if she had been aware that this change was present. See the resultant New Grounds of Rejection included herein. Claims 2 and 8 have been canceled. Claims 1, 3-7, and 9-18 are still at issue and are present for examination. Claims 10-17 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/3/07.

Claims 1, 3-7, 9 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 (upon which claims 3-7, 9 and 18 depend) is confusing in the recitation "a microorganism that converts carbon to PHA primary carbon source" as it is unclear what this in fact means. Taken literally it would appear to mean a

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microorganism that can transform elemental carbon to any primary carbon source for PHA biosynthesis (glucose, xylose, sucrose etc.) however, clearly this is not what the application describes. Alternative explanations could be that this was intended to read "a microorganism that converts carbon to PHA, a primary carbon source" or as the claim was previously "a microorganism that converts carbon to PHA, a quantity of xylose as a primary carbon source". Furthermore, claims 3, 7 and 9, lack antecedent basis for "the xylose", and the "ratio of xylose to levulinic acid" as claim 1 does not currently refer to xylose. For purposes of further examination it is presumed that "a microorganism that converts carbon to PHA, a quantity of xylose as a primary carbon source" was intended as this is the language which is consistent with the specification, the dependent claims and the prosecution history of the instant application.

Claim 9 is confusing in the recitation of "the ratio of xylose to levulinic acid in the medium after the second addition of levulinic acid is from about 0.01 to 1.0". However this is confusing as xylose is recited as the primary carbon source and thus should be in greater quantity, and is not what the specification describes as in all instances described in the specification the amount of xylose is greater than the amount of

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levulinic acid used. It would appear that this should recite the ratio of levulinic acid to xylose. This rejection has been previously presented as an objection since it appeared to be simply a typographic error but as applicant has twice not corrected the problem it is now made a rejection as applicants lack of correction imply this is not the case

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-7, 9 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Lee, Ramsay et al., Bertrand et al., Chung et al. and Jang et al. (all cited on the IDS of 9/16/05).

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Each of Lee, Ramsay et al. and Bertrand et al. teach the production of the polyhydroxyalkanoate PHB with a microorganism using the sugar xylose as the main carbon source. Each of Ramsay et al. and Bertrand et al. specifically derived the xylose used for the PHB production from a hemicellulose hydrosylate. None of Lee, Ramsay et al. and Bertrand et al. used levulinic acid as a cosubstrate for the production of P(3HB-co-3HV).

Each of Chung et al. and Jang et al. teach the production of the polyhydroxyalkanoate P(3HB-co-3HV) with a microorganism using glucose as a primary carbon source and levulinic acid as a secondary carbon source. Chung et al. used ratios of levulinic acid/glucose of 0-0.2 while Jang et al. used ratios of 0-0.1. They teach that P(3HB-co-3HV) is a particularly useful PHA having a range of desirable thermomechanical properties of interest and that levulinic acid is cheaper and more effectively utilized as a cosubstrate for production of P(3HB-co-3HV) than other known cosubstrates. Chung et al. also teach addition of additional amounts of levulinic acid to the culture after an period of several hours in order to maintain the level of LA in the culture at a constant amount and Jang et al. and Chung et al. teach that the ratio of HV to HB can be modulated by adjusting the ratio of the primary and secondary carbon sources,

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i.e., increased amounts of HV in the copolymer are produced by increased amounts of the cosubstrate. Furthermore, Jang et al. teach that low levels of levulinic acid addition (i.e., 0.5 g/L) was very effective for stimulating cell growth as well as for copolymer accumulation (see page 222).

The skilled artisan is well aware that PHA accumulation in most microorganisms does not occur linearly during the growth phase but occurs only after nitrogen depletion of media begins (see Figure 2 of Bertrand and Fig 1 of Ramsey et al.) and that cosubstrates used to produce the HV unit of P(3HB-co-3HV) are often growth inhibitory at high concentrations. As such many P(3HB-co-3HV) cultivations are done as two stage cultivations including an initial growth phase on the primary substrate followed by addition of the cosubstrate at the time of nitrogen depletion and PHA accumulation. However, as Jang et al. teach that low levels of levulinic acid are actually growth stimulatory and as Lee, Ramsay et al. and Bertrand et al. all teach that xylose is a much cheaper primary carbon source for PHB production, it would have been obvious to add low amounts of levulinic acid to the cultures of the microorganisms of any of Lee, Ramsay et al. and Bertrand et al. at the beginning of the culture and to add a larger amount of levulinic acid as a cosubstrate at the time of nitrogen depletion (at approximately

16-30 hrs in the cultures of Bertrand et al. and Ramsey et al., see Figure 2 of Bertrand and Fig 1 of Ramsey et al.) in order to produce P(3HB-co-3HV) in these microorganisms from the cheaper primary carbon source xylose.

Applicants argue that the claims include the limitation that a second, larger quantity of levulinic acid is added between about 16 hours and about 24 hours after the addition of a first, smaller quantity of levulinic acid and that none of the cited references teaches or suggests a second, larger addition of levulinic acid. However, this is not persuasive as the rejection explains why a skilled artisan would have found this obvious. As discussed in the rejection the disclosure of Jang et al. teaches that low levels of levulinic acid are growth stimulatory while both Jang et al. and Chung et al. teach that high levels of LA increase the mol % of HV in the copolymer but are growth inhibitory. A skilled artisan which is attempting to produce high levels of the P(3HB-co-3HV) copolymer would use growth stimulatory amounts of levulinic acid during the growth phase (before PHA production begins) in order to achieve the highest possible level of microorganism in the culture prior to the introduction of a growth inhibitory substance (i.e. the levels of levulinic acid necessary for sufficient HV incorporation to occur) and then to add additional higher levels

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of LA as necessary for copolymer production at the time of nitrogen depletion in order to provide to for production of the P(3HB-co-3HV) copolymer with sufficient levels of the HV monomer. As such while the references do not explicitly suggest the limitation of the claims the teaching of the cited references in combination with the knowledge of the skilled artisan would have suggested this method.

Applicants argue that Bertrand et. al teaches the addition of propionic acid (PA) as a secondary carbon source but does not teach a two-stage addition of the secondary carbon source with the second addition being in a quantity greater than the first. Lee and Ramsay et al. do not teach the addition of a secondary carbon source at all, Jang et al. teaches the addition of LA as a secondary carbon source but does not teach the subsequent addition of LA to the culture after the first addition of LA. and Chung et al. teaches the use of LA as a secondary carbon source and teaches the use of additional amounts of LA to maintain the level of LA in the culture at a constant amount and thus none of the references teach the addition of a first and second quantity of a secondary carbon source with the second quantity being greater than the first quantity. While this is a true statement it is noted that the instant rejection is made under 103 and not under 102 and includes a well reasoned

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explanation as to why a skilled artisan given the disclosure of all of these references would have found it obvious to do just this. Merely because none of the references did so or explicitly suggested doing so is not evidence that the combined disclosures do not in fact suggest what is claimed. The rationale advanced in the instant rejection is clearly based on the various facts provided by the cited references and NOT on facts disclosed by applicants and thus does provide a *prima facie* case of obviousness.

Applicants argue that neither Chung et al. nor Jang et al. teach or suggest the use of xylose as a primary carbon source. This is noted but applicants are reminded that the rejection was not made over only the Chung et al. and Jang et al. references but over the combination of these references with Lee, Ramsay et al. and Bertrand et al. Each of these three references teach the use of xylose as the primary carbon source for PHB production and why (i.e., cheaper cost of xylose) a skilled artisan would select xylose as primary carbon source instead of glucose as used by Chung et al. and Jang et al. As such the combination of reference cited by the examiner does suggest the use of xylose as the primary carbon source.

For all the reasons discussed above, the rejection is maintained.

Applicant's after-final amendment which was inadvertently entered necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed, can be reached at (571) 272-0934. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval

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(PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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